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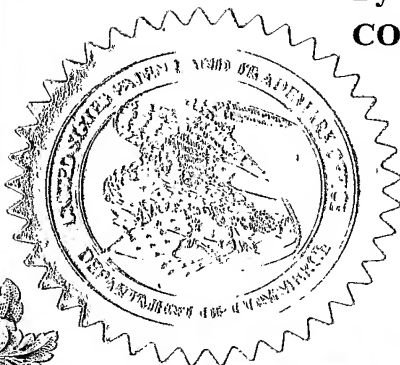
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APPLICATION NUMBER: 60/549,553

FILING DATE: *March 04, 2004*

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P. SWAIN
Certifying Officer

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a **PROVISIONAL APPLICATION FOR PATENT** under 37 CFR 1.53 (b)(2).

Docket Number		27719		Type a plus sign (+) inside this box ->	+
INVENTOR(s) / APPLICANT(s)					
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)		
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TITLE OF THE INVENTION (280 characters max)					
ARTHROSCOPIC SUTURE CUTTER					
CORRESPONDENCE ADDRESS					
G. E. EHRLICH (1995) LTD. c/o ANTHONY CASTORINA 2001 JEFFERSON DAVIS HIGHWAY SUITE 207					
STATE	VIRGINIA	ZIP CODE	22202	COUNTRY	USA
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	6	<input checked="" type="checkbox"/> Applicant is entitled to Small Entity Status		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	2	<input checked="" type="checkbox"/> Other (specify) 3 Claims		
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees			FILING FEE AMOUNT (\$)		\$ 80.-
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number:			50-1407		

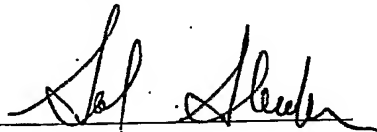
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No

☐ Yes, the name of the US Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE



1 March 2004

Date

25,457

REGISTRATION NO.
(if appropriate)

TYPED or PRINTED NAME SOL SHEINBEIN

☐ Additional inventors are being named on separately numbered sheets attached hereto

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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1
APPLICATION FOR PATENT - DRAFT

5 Inventor(s): Ran OREN, Dan MOOR

Title: ARTHROSCOPIC SUTURE CUTTER

10

BACKGROUND: SUTURING IN ARTHROSCOPY

15 There is a growing demand to perform surgery, wherever possible, through small portals leading directly to the location operated on, thus avoiding excessive damage to overlying and adjacent tissue. The technique is also known by the name endoscopy. Arthroscopy is the term used for the endoscopic approach applied to treat the various limb joints in the body. As
20 in all minimally invasive techniques, the area operated on is not exposed and is not directly visible to the surgeon. He relies on a system of internal illumination and a small video camera, which projects an enlarged image onto a monitor screen. The surgeon is guided by this image.

All operations necessary must be performed through a narrow opening, the
25 size of which limits the size of the instruments used and the space available to manipulate them. In particular, access to tight joints is difficult. Small-size cutting, grasping, debriding and piercing instruments, capable of operating through small portals, have been developed for this purpose. Suturing is also possible and many suture passing and stitching devices are available to the
30 arthroscopist. Tying a knot *in situ* is, however, barely possible.

The alternative solution is to use excess lengths of suture and bring the end of the strands to the outside for easy tying. One of several types of sliding knots, similar to the "hangman's knot", is formed at the outside and then, aided by one of several types of knot manipulating instruments, is moved
35 down the remaining strand through the access portal and is tightened firmly over the tissue stitched. The excess length of suture is now cut off a small distance above the knot.

Therefore, the features to be observed in any design for an arthroscopic suture cutter include small diameter, ease of use, clean cutting and controlled distance of cut from the knot. The length of the suture end remaining after cutting is an important feature: if it is too long, it may cause irritation, if it is too short, the knot may fail to hold. Ideally, the instrument should be able to handle and cut all types and sizes of suture material in use.

In practice, all instruments available on the market fail to satisfy one or more of these criteria.

One such device, which has been on the market since 1999 and offers several advantages over others, consists of a pair of loop handles, an elongated tube and a solid shaft mounted within the tube. A tunnel sized to allow suture to be threaded through it is formed through the distal section of the shaft at an angle to its axis. The cross section of this tunnel is in the form of a droplet, and the angle relative to the axis of the shaft causes the exit to be much elongated in shape. The distal, entry opening of the shaft is countersunk to accommodate the knot. The shaft slides freely within a hardened tube, the distal end of which is ground into a sharp cutting edge. Sliding the tube forward relative to the shaft will force a suture threaded through the tunnel, irrespective of its thickness, against the narrow, tapered portion of the tunnel exit for clean cutting. The tube is advanced until it cuts the suture at a length determined by the distance between the distal end of the shaft and the tunnel exit.

In use, after threading the free end of the suture strand into the shaft, the surgeon holds the end of the suture while advancing the instrument along the suture strand until the knot is reached. A spring loaded safety catch in the handle prevents accidental premature cutting. Releasing the catch allows the surgeon to operate the moveable handle for performing the cutting.

One shortcoming of the said device is that it is difficult to thread the suture through the tunnel, especially in the conditions prevailing in the operating room. Many surgeons prefer to use other devices, such as suture scissors, where the suture remains free, thus sacrificing important advantages for

easier use. Also the practicable dimensions of the tunnel restrict the range of suture types for which the device can be used.

SUMMARY OF THE INVENTION

- 5 The present invention addresses the shortcomings of the device described above.
- In place of the closed tunnel, a slot is opened, leading from the distal end to a predetermined point along the shaft. At least one narrow V-shaped notch is formed at the exit.
- 10 The main advantage of the invention is that the suture can be engaged from the open side of the slot, thus avoiding the need for introducing the suture into a closed tunnel. In addition, the width of the slot, the length of cut-off and the shape of the exit are flexible and can be modified to accept new types of suture.
- 15 A tubular knife fitting over the shaft is used, as in the prior art device. Any suitable operating mechanism for sliding the knife, which incorporates a safety catch, may be employed.

BRIEF DESCRIPTION OF THE DRAWINGS

- 20 The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of
- 25 providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art
- 30 how the invention may be embodied in practice.

FIG.1 is a schematic drawing of the prior art device for information only,

showing the shaft (1), the tunnel (2), the tubular knife (3), the safety catch (4) and the moveable handle (5).

FIG. 1A depicts the enlarged cross-section of the tunnel.

FIG. 2 shows the improved configuration of the distal end of the shaft, illustrating the solid shaft body (1), the countersink for engaging the knot (2), the open slot at the side ((3) and the V-shaped notch (4).

FIG. 3 illustrates the shaft with a knotted suture engaged in the slot.

MAKING AND USING THE INVENTION

The materials used for the shaft and tube are suitable grades of surgical non-corrosive steel. No special manufacturing techniques are required to make the device beyond those available for surgical instrument manufacturers.

The use of the new device would be identical to the predicate device's use, except for the method of engaging the suture. With the present invention the surgeon simply holds the suture taut and brings the instrument's slot into engagement with the suture (see Figs. 2&3). The surgeon then slides the instrument down along the suture until the knot is met. Notably, the slot should be dimensioned so that the knot remains in the countersink and does not enter the slot. The surgeon then checks that the suture lies at the opening of the V-notch, or, if needed, manipulates the instrument until such position is reached. He now releases the safety catch and operates the cutting mechanism. It should be noted that the one device could also be used both for positioning and tightening the preformed knot and for cutting off the excess length.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated

in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be
5 construed as an admission that such reference is available as prior art to the present invention.

WHAT IS CLAIMED IS:

1. An endoscopic suturing device comprising a shaft attached to a handle being for positioning a distal portion of said shaft within a tissue to be sutured, wherein said distal portion of said shaft includes a slot configured so as to enable engaging a suture and advancing a knot thereupon.

2. The endoscopic device of claim 1, wherein an end of said slot is configured with a V-shaped groove being capable of cutting suture placed therein.

3. A method of suturing tissue utilizing the endoscopic device of claim 1.

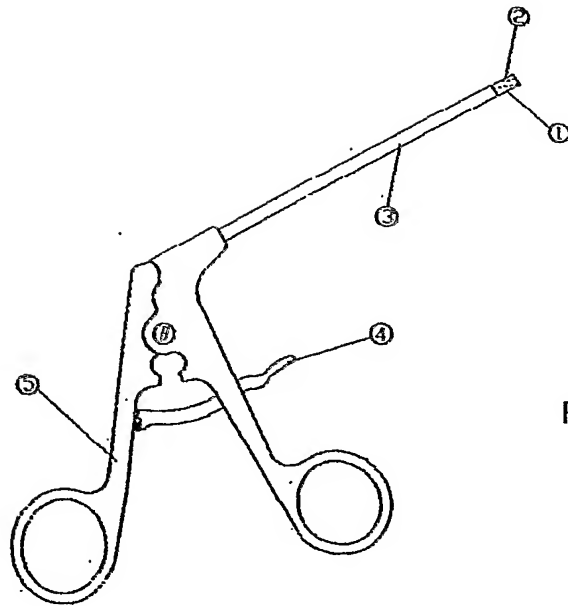


FIG. 1A

FIG. 1

